AmerisourceBergen

ORDER MONITORING PROGRAM **Policies and Procedures**

Policy Number: **CSRA 2.12**		Effective:	December 1, 2005
Written/revised by: Steve Mays		Revised:	October 1, 2008

PURPOSE

To ensure compliance with applicable state and federal regulations, AmerisourceBergen Corporation (ABC) has designed this program to review the ordering activity of its customers to identify possible excessive or suspicious orders of controlled substances and listed chemicals.

POLICY

Corporate Security & Regulatory Affairs (CSRA) and Distribution Center (DC) management will be responsible for identifying potentially excessive or suspicious customer orders of controlled substances or listed chemicals and will initiate an appropriate investigation when possible indicators of such activity are identified.

As part of ABC's efforts to identify and monitor suspicious orders, every associate should report to CSRA any information regarding any potentially excessive or suspicious order of controlled substances or listed chemicals by any ABC customer.

OVERVIEW OF PROCEDURE

Investigations into possible excessive/suspicious orders may be initiated through many sources, including:

1. Controlled Substance/Listed Chemical Order Monitoring Program (OMP)
2. US Drug Enforcement Administration (DEA)
3. Distribution Center personnel or other ABC associates
4. Analysis of monthly reports that identify the top purchasers of certain identified controlled and non-controlled substances.

A. Controlled Substance/Listed Chemical Order Monitoring Program

The following procedures will be conducted as part of the Controlled Substance/Listed Chemical Order Monitoring Program:

1. ABC has developed an Order Monitoring Program (OMP) for controlled substances and listed chemicals. (See attached Exhibit A.)

2. On a daily basis, CSRA will review an order monitoring report that identifies ABC customers that placed orders which exceed thresholds established by ABC. CSRA will review all orders in the "Hold" or "Cancelled" status to determine whether or not the orders are suspicious. Orders that are determined to be possibly suspicious will be investigated and reported to DEA without being shipped. CSRA will also review orders that exceeded such thresholds but were released by DC personnel to help ensure that decisions are being made appropriately and whether follow-up is necessary, including training or other communication or making an adjustment to guidelines for one or more customers.

3. On a monthly basis, CSRA will review a customer product-mix report to help identify customers purchasing more than a pre-determined percentage of controlled substances vs. non-controlled substances. CSRA will investigate and identify customers whose purchasing activity warrants further review.

4. On a monthly basis, CSRA will review the top purchasers in the ABC customer base of certain controlled and non-controlled substances including but not limited to Hydrocodone combination products, Oxycodone combination products, Tramadol and Carisoprodol. If warranted, CSRA will conduct a targeted visit at the customer's location to make certain the customer is substantially compliant with all applicable federal and state statutes and regulations.

5. For each customer identified in steps 2 or 3, CSRA will review any previous due diligence, including new customer set-up information, or suspicious order investigations, as well as a one-year purchase history for applicable controlled substances, listed chemicals or both if necessary to determine the customer's previous purchasing patterns.

6. A CSRA investigator will consult with appropriate DC personnel and the responsible sales associate about the customer's ordering patterns. If the investigator determines that further investigation is appropriate, additional investigative steps will be taken. Those may include completion of an ABC Questionnaire by the customer or a site visit by an ABC associate. (See CSRA I Form 590 for retail customers and CSRA I Form 590e for distributors.) Typically, CSRA will try to complete any such investigation within two (2) business days.

7. The CSRA investigator will conduct a final review with the Manager, Diversion Control Program after all relevant information has been obtained and recommend an appropriate resolution (e.g., terminate account or suspend the customer's ability to order one or more of the following: all controlled substances, all listed chemicals, all controlled substances within one or more specific schedules, such as C-IIs, or a specific drug family, such as hydrocodone solids). The CSRA investigator's recommendation will identify which DC manager (DCM) and which sales associate are responsible for the account.

8. The standard ABC will use is whether it is more likely than not that the customer is permitting controlled substances to be illegally diverted, whether knowingly or due to its negligence in complying with its legal obligations for professional practice. If so, ABC will cut-off further sales of controlled substances or listed chemicals that appear are being diverted. Decisions will be made on a case-by-case basis and will depend upon a full consideration of circumstances, including:

- Ordering patterns of the customer (for example, is it mostly the highest dosage units of hydrocodone or is there a wide range of dosage units).
- Product mix (controlled substances compared with other drugs as well as which controlled substances).
- Size and frequency of the orders.
- Publicly available information about the pharmacy, including on the internet.
- Whether customer has an NCPDP number (used to bill insurance companies and other third party payors).
- Whether patients are disproportionately "cash customers."
- Other information provided to CSRA by the customer or others.
- At the discretion of the Manager, Diversion Control Program, and in consultation with CSRA Senior Management, CSRA may choose to conduct a targeted visit of the customer location. This visit is to determine if the customer is substantially compliant with state and federal statutes and regulations.

9. The Manager, Diversion Control Program will make a decision and (1) inform the appropriate DCM and responsible sales associate and (2) advise appropriate members of the Suspicious Order Oversight Team, including the CSRA VP, ABC's General Counsel, and the appropriate Regional VP (or their designees).

10. Any decision by the Manager, Diversion Control Program will be final after 48 hours unless a member of the Suspicious Order Oversight Team requests that it be reviewed. The Manager, Diversion Control Program may request guidance from members of the Suspicious Order Oversight Team when there are novel or unusual circumstances or the Manager, Diversion Control Program is otherwise uncertain what decision to make. And, the DCM or responsible sales associate may request that the Suspicious Order Oversight Team review the Manager, Diversion Control Program decision. Guidance sought from and direction given by the Suspicious Order Oversight Team will be through or under the direction of an ABC attorney. The Suspicious Order Oversight Team will typically review CSRA's full investigation file and the customer's file from the DC. The CSRA investigative file will include one year's purchasing history for the customer, including volume and mix of product, the questionnaire (CSRA I Form 590) obtained from the customer, any publicly available information collected by CSRA about the customer, such as from an internet search, and information from an on-site visit by an ABC associate.

11. When a decision to terminate an account or suspend a customer's ability to order one or more drugs or listed chemicals is final (i.e., after 48 hours or when the Suspicious Order Oversight Team makes its decision), the Manager, Diversion Control Program will notify the Regional VP, the DCM, the responsible sales associate, and Regional Account Maintenance. Regional Account Maintenance will confirm by e-mail

to the CSRA Director that all requested changes to the account were made. The DCM and sales associate are responsible for notifying the customer, any GPO/buying groups, and other operations and sales personnel, etc.

12. CSRA may decide to keep an account open with no changes or, based on its investigation, may decide to increase one or more OMP thresholds applicable to an account.

13. Based on its investigation, CSRA may decide that it will not keep a customer's account open (with or without the ability to purchase controlled substances and listed chemicals) unless the customer has made changes in its operations and agrees to maintain such changes. For example, a customer may have been investigated by CSRA as the result of questionable sales through an internet pharmacy. If the customer subsequently discontinues such suspicious activity, CSRA may require that, to keep the account open, the pharmacy agree to sign one of the following documents:

a. **Non-Internet Pharmacy Compliance Agreement (CSRA I Form 590n)**
If the customer does not participate in an internet pharmacy operation, an authorized customer representative will be required to sign a Non-Internet Pharmacy Agreement (CRSA I Form 590n).

b. **Internet/Mail Order Pharmacy Compliance Agreement (CSRA I Form 590b)**
If the customer participates in an internet pharmacy in which controlled substances are dispensed, an authorized customer representative will be required to sign an Internet Pharmacy Compliance Agreement (CSRA I Form 590b).

14. If the customer declines to sign either such agreement, CSRA will either terminate the account or suspend the customer's ability to order one or more drugs or listed chemicals.

15. CSRA will keep a copy of its decision, as well as reasons for making its decision, in the customer's file, together with a copy of any Pharmacy Compliance Agreement signed by the customer. CSRA will provide a copy of its decision to the DC, which will keep a copy in the customer's DC file. CSRA will, from time to time, monitor or re-investigate any account that has been kept open subject to the customer agreeing to special obligations to help ensure compliance.

16. CSRA will notify DEA of any suspicious orders, including any action to terminate an account or restrict a customer's ability to order controlled substances or listed chemicals.

17. CSRA will place on its “Do Not Ship List” any customer that CSRA closes or where CSRA restricts the customer's ability to order controlled substances or listed chemicals.

B. Notification by DEA

If ABC receives notice from the DEA of possibly excessive or suspicious purchasing activity, CSRA will follow Steps 4 through 16 above, including notice to DEA of any decision upon completion of the investigation.

C. Notification to Distribution Center

If an ABC Distribution Center receives notice of possibly excessive or suspicious purchasing activity from any other source, it will notify CSRA and CSRA will follow Steps 4 through 16 above.

D. Re-Establishing A Closed Account

An account on ABC's “Do Not Ship List” will not be re-opened unless the customer meets all requirements for a new customer, including an on-site inspection. Additionally, the Suspicious Order Oversight Team must approve the account before it is re-opened. Typically, the Suspicious Order Oversight Team will review CSRA's full investigation file and the customer's file from the DC and will document all changes that occurred after ABC's decision to place the account on the "Do Not Ship List." If the account is re-opened, the Suspicious Order Oversight Team will document the reasons for changing the earlier decision. In re-opening the account, ABC may require that the customer agree to special terms (e.g., lower thresholds for controlled drugs or listed chemicals) and CSRA will periodically monitor or re-investigate to help ensure compliance. Re-opening a closed account should be infrequent.